



T1D
Exchange

QI Project: Screening for stage 1 And stage 2 type 1 diabetes

May 24, 2024

Agenda

- Introduction/Welcome
- Screening project overview (Aim/Expectations)
- Lessons learned
- Participating centers
- Timeline
- Deliverables/Next Steps
- Questions

Timeline	Expectations
May 2024	<ul style="list-style-type: none">• Hold Kickoff meeting/Plan recurring coaching calls
June 2024	<ul style="list-style-type: none">• Attend monthly group coaching calls• Teams map out current process and annotate pain points in the process• Execute Statements of Work (SOW)
July 2024	<ul style="list-style-type: none">• Attend monthly group coaching calls• Create and share fishbone diagrams• Create first PDSA Cycles.• All centers will report baseline data to Smartsheet (January 2024 to June 2024)

AIM Statements

Increase by at least 15% (from baseline) the proportion of people screened for T1D in 18 months. (June 2024- December 2025)

Increase by at least 30% (from baseline) the proportion of eligible people monitored for progression to stage 3 T1D over 18 months. (June 2024-December 2025)

Project Metrics

Screening

A) Number of individuals seen in reporting month who have been screened for T1D antibodies

Autoantibody Screening

1) Number of individuals in [A] that have been screened and confirmed positive for antibodies (GAD65, Anti-IA2, Tyrosine Phosphatases IA2 and IA-2 β , ZnT8)

1a) Number of individuals in [A] that have been confirmed positive for a single autoantibody

1b) Number of individuals in [A] that have been confirmed positive for multiple autoantibodies

Stage 1 Diagnosis

2) Number of individuals in [A] who have multiple islet autoantibodies, normal blood glucose

Stage 2 Diagnosis

3) Number of individuals in [A] who have multiple islet autoantibodies, abnormal glucose tolerance OR HbA1c 5.7-6.4%

Stage 3 Diagnosis/New Onset Patients

4) Number of individuals in [A] who have blood glucose levels above ADA diagnostic thresholds OR HbA1c \geq 6.5%

Project Metrics

Monitoring

5) Number of individuals in [2] + [3] with a scheduled endocrinology (per monitoring guidelines)*

DKA Events

6) Number of individuals monitored for T1D diagnosis in last 12 months who have a DKA in reporting month

Intervention

7) Number of individuals in [4] offered Teplizumab prescription



Previous Highlights and Lessons Learned



Rady Children's Hospital/ UC San Diego School of Medicine

Clinical Implementation of Autoantibody Screening (T1DX-QI) at Rady Children's Hospital, San Diego

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May 24th, 2024

Rady Children's Hospital-San Diego

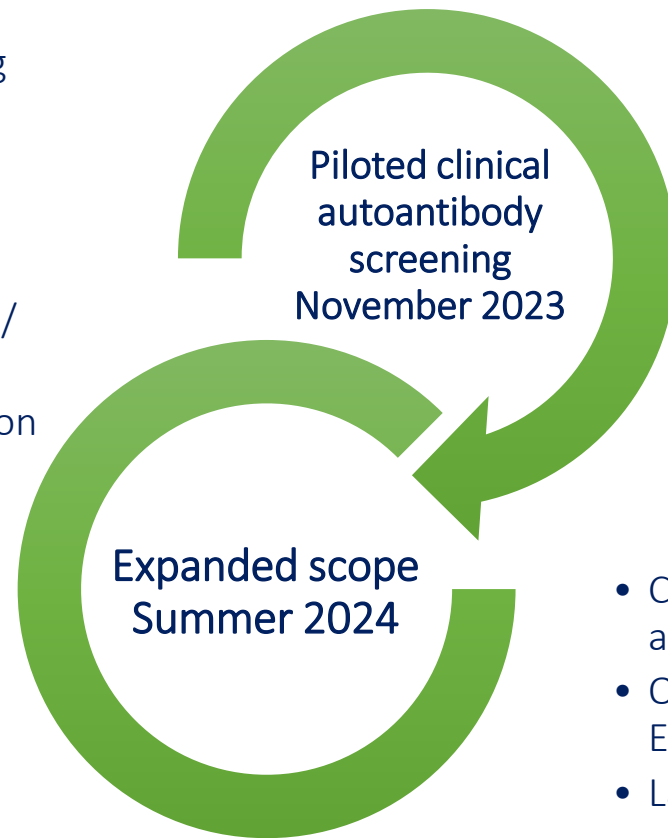
UC San Diego
SCHOOL OF MEDICINE



RCHSD Clinical Implementation of Autoantibody Screening (T1DX QI)

BEFORE November 2023:

- Not a TrialNet site
- No Autoantibody Screening workflow
- Some providers referring families to TrialNet
- Difficult to follow up, track results or offer surveillance/treatment
- Unable to order screening on siblings who are not our patients without PMD referral



- Partnership with ASK program- screening kits offered in clinic- no need for PMD referral
- Started with 1 provider's diabetes clinic (T1D first degree relatives 2-18 years old)
- 6/16 positivity rate (3 at Stage 1, 2 at Stage 2 1 at Stage 3)
- 2 no shows
- 16 scheduled
- 5 need to schedule

- Currently expanded to all 10 provider's (5 actively referring)
- Offer screening at Diabetes Events (Diabetes Education Day, Diabetes Summer Camp)
- Launch "T1D at risk" Clinic

RCHSD Experience & Lessons Learned

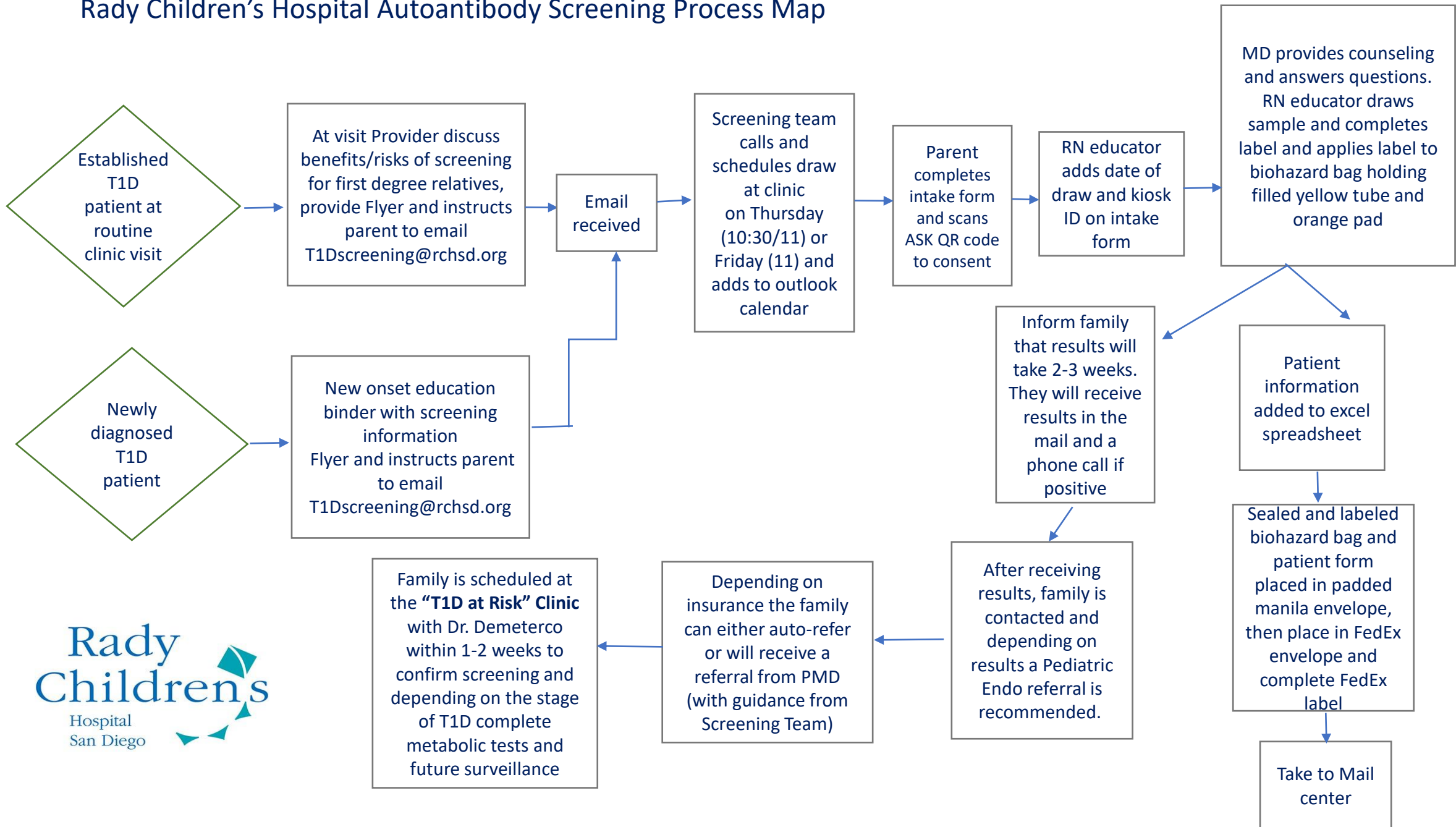
Facilitators

- Information Flyer available at the outpatient and inpatient setting
- T1Dscreening@rchsd.org email created and shared among the screening team
- Screening Team access to the email – Track all referred patients
- Partnership with the ASK program at Barbara Davis with screening kits available in clinic
- No cost to family, no insurance issues
- Note template/JDRF monitoring consensus
- Unique referral to “T1D at-risk” clinic

Barriers

- Provider education and buy-in
- Screening time and reimbursement
- Pre-screening counseling time and reimbursement
- Creating new MRN, obtaining referrals to Pediatric Endocrinology
- Waiting time for results
- Time/cost/training re: collecting screening sample

Rady Children's Hospital Autoantibody Screening Process Map



RCHSD Autoantibody Screening Informational Flyer

What happens if my screening is positive?

If the test finds 1+ autoantibody, a lab draw is recommended to confirm results. If confirmed, you will be referred to a pediatric endocrinologist for further monitoring and counseling.

If the test finds 2 or more + autoantibodies, a lab draw is recommended to confirm results. If confirmed, you will be referred to a Pediatric Endocrinologist for monitoring and counseling and, if indicated, to discuss possible treatment options or clinical trials to help delay the progression of T1D

How do I get screened?

Email us at
T1Dscreening@rchsd.org to
set up appointment.

Appointments available on Thursdays and Fridays. Screening is done with a fingerprick. Please scan and complete e-consent for each child being screened. Please complete prior to screening visit and bring kiosk number.



E- consent
Kiosk
ID_____

How will I receive results?

Results will be sent via mail and/or phone call. Results can take up to 2-3 weeks.

Screening for Type 1 diabetes(T1D)

We are offering free screening to first degree relatives 18 years and younger of our patients who are living with T1D. Knowing if one is in the early stages of T1D, you can better prepare to recognize symptoms when they do appear. This can help you understand what's ahead and lower the risk of serious complications of diabetic ketoacidosis (DKA). There are proteins that appear in the blood when T1D begins, even in early stages before there are symptoms. The current screening kit we use will also check for celiac disease antibodies.



Stage 1 of developing type 1 diabetes

2 or more autoantibodies present. The immune system has begun to attack the beta cells in the pancreas. There are a lot of healthy beta cells left at this time. The body is able to produce enough insulin to keep blood sugars normal. There are no symptoms.

www.screenfortype1.com

Stage 2 of developing type 1 diabetes

Starts when enough beta cells have been destroyed that the body is no longer able to keep blood sugars normal all of the time. At this stage, people do not notice any symptoms. High blood sugars may appear in response to a sugar challenge. Hemoglobin A1C may be higher in this stage.



Our screening kits are provided by the ASK program/Barbara Davis Center

Stage 3 of developing type 1 diabetes

Most of the beta cells have been destroyed. The beta cells that are left cannot produce enough insulin to keep blood sugars normal. Symptoms of T1D start to occur and become more severe over time. If necessary medical treatment is not started, this can be life threatening.

www.askhealth.org



University of Florida

Clinical Implementation of Autoantibody Screening (T1DX QI)

Built on our research screening experience

- TrialNet screening T1D relatives: 2-45yo FDR; 2-20yo other relatives
- UF last 4 months, 149 screens with 11 positive (7%)

Piloted clinical autoantibody screening late 2023

- 1 provider's diabetes clinic (T1D relatives)
- 8/17 positivity rate

Expanded scope summer 2024

- Multiple providers' diabetes clinics (T1D relatives)
- Ped endocrine clinics (pre-screen for auto-immune diagnoses)

UF Experience & Lessons Learned

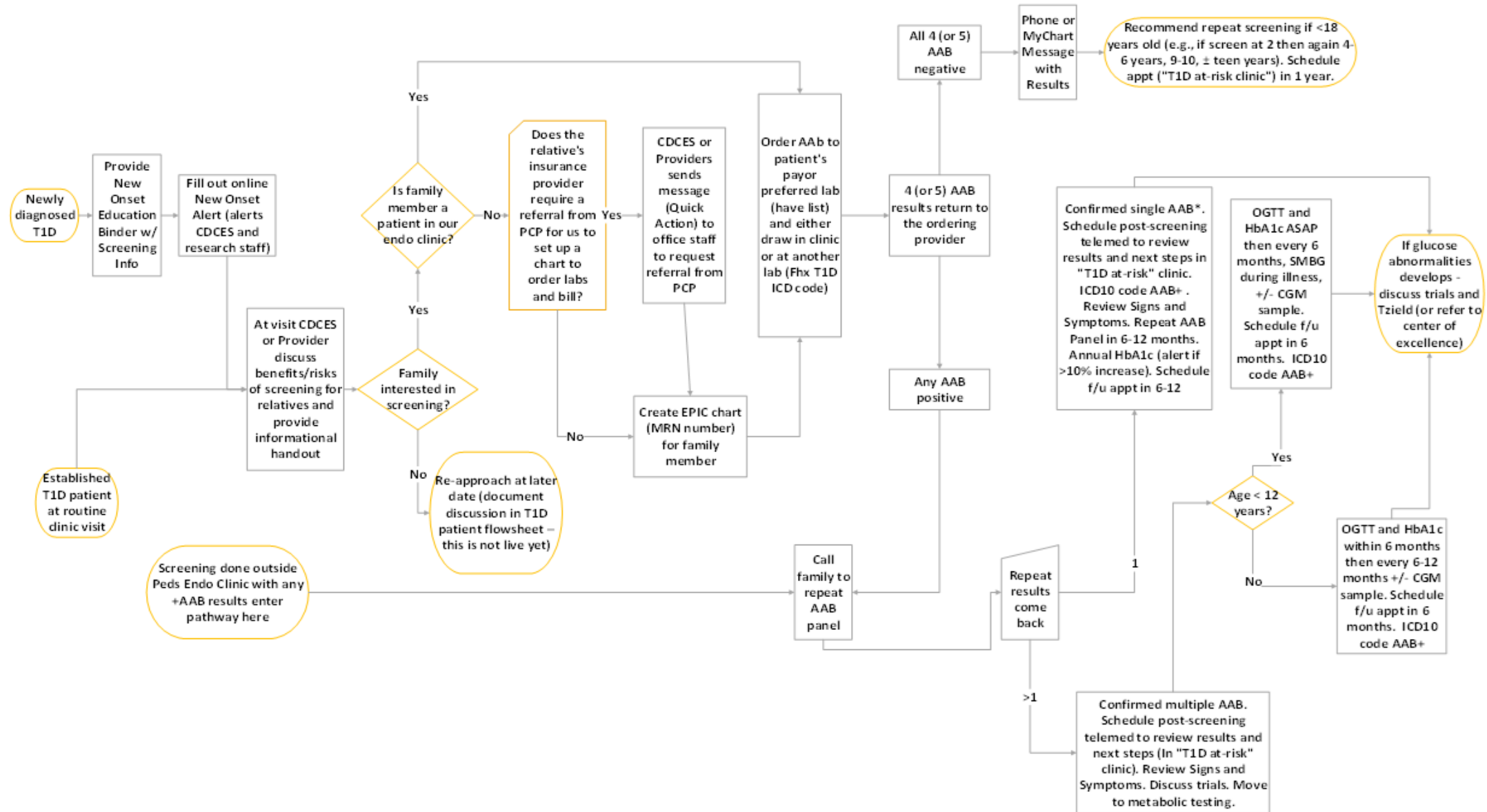
Facilitators

- Coordinator sees families at end of visit
- ICD10 code Z83.3 (Family history of type 1 diabetes) so far has been covered at local labs by insurers
- Once AAB+, ICD10 code R76.8
 - *Effective 10/1/24 “T1D presymptomatic” codes – courtesy of Dr. Frohnert*
- Note template/JDRF monitoring consensus
- Unique referral and clinic for “T1D at-risk”

Barriers

- Time to screen & RVU reimbursement
- Creating new MRN
- Documentation of who approached
- Need for pre-screening counseling especially for non-relatives (concerns re: insurance coverage, anxiety, etc.)
- Time/cost/training re: metabolic monitoring (SMBG, OGTT, CGM)
 - Glucola in clinic; CGM samples?

UF T1DX-QI/JDRF AAB Screening and Metabolic Monitoring (*treat confirmed single IA2A as multiple)





Participating Centers Current T1D Screening Programs



Texas Children's Hospital/Baylor College of Medicine

Baylor
College of
Medicine

DEPARTMENT OF
PEDIATRICS



Division of Pediatric Diabetes & Endocrinology

Texas Children's: T1D Screening Program

Daniel DeSalvo, MD

May 2024



SIT Down T1D! - Screening & Intervention To Delay T1D

Relative of Someone with T1D?

You (or your child) may be eligible for Texas Children's Type 1 Diabetes Screening & Prevention Program.

Who is eligible for the Texas Children's Type 1 Diabetes (T1D) Screening & Prevention Program?

Family members of a person with T1D who are under the age of 18. In most cases, this will be the sibling of someone with T1D.

What is the risk of developing T1D in family members?

- Those with a family member with T1D have a 1 in 20 risk of developing T1D, which is about 15 times higher than those without a family history.

What is the benefit of screening for T1D?

- There are ways to identify people with early stages of T1D – even before symptoms and the need for insulin arise. One way to identify early stages of T1D includes screening for autoantibodies, which indicate the autoimmune process in the pancreas has begun.
- By identifying T1D early, it may be possible to prevent the onset of diabetic ketoacidosis (DKA).
- We now have an FDA-approved medication for patients 8 years and older. Tzield (teplizumab) has been shown to delay the onset of insulin-required T1D by approximately 2 years, on average.

What does the T1D Screening & Prevention Program entail?

- Telemedicine visit(s) with a Texas Children's Diabetes & Endocrinology provider.
- Laboratory screening for autoantibodies, staging of T1D, monitoring for progression and counseling on teplizumab if eligible.

How do I schedule a T1D screening & prevention visit?

- Talk to your PCP about a referral for T1D screening and prevention at Texas Children's.
- Depending on your insurance, you may be able to schedule a screening on MyChart or by calling central scheduling at 832-822-2778

Symptoms of Type 1 Diabetes include

- Frequent Urination
- Extreme Thirst
- Dry Mouth
- Fatigue and Weakness
- Increased Appetite
- Unexplained Weight Loss
- Slow Healing Cuts

STAGE 1
Two or more autoantibodies can be identified, but blood sugar levels are normal, and the person has no symptoms.

STAGE 2
Two or more autoantibodies can be identified, and blood sugar levels are not normal, but most people still have no symptoms.

STAGE 3
Two or more autoantibodies can be identified, blood sugar levels are high, and the person typically has symptoms.

For more information, visit [texaschildrens.org](https://www.texaschildrens.org)



- Telemedicine clinic with **Lauren Culbreth, PA-C** to start June 2024
- **Epic Pop Health T1D Screening Registry**, Smartform, documentation, dashboard, and reports
- PCPs can refer siblings for **“Screening and staging to delay type 1 diabetes”**
- **TCP webinar** scheduled for summer

SmartForm for T1D Screening & Staging

SmartForm Designer - ENDO TZIELD INTAKE SMARTFORM [1762] - General

Diabetes Intake

Diabetes staging (puts patient on prevention registry)

Pre-screening (autoantibodies not yet obtained) | Screening (all autoantibodies negative)

Screening (only 1 autoantibody positive) | Stage 1 T1D

Stage 2 T1D | Stage 3 T1D

Family member with T1D

Sibling | Aunt | 2nd Cousin | No known family members with T1D

Mom | Uncle | Grandmother | Other

Dad | 1st Cousin | Grandfather

Stage 1 T1D status

known | NA | unknown | other

Stage 1 T1D date

Stage 2 T1D status

known | NA | unknown | other

Stage 2 T1D date

Method of detecting dysglycemia

Fasting BG | Random BG | HbA1c | OGTT

CGM | Other

Stage 3 T1D status

known | NA | unknown | other

Stage 3 T1D date

Positive antibodies

GAD65 Glutamic acid decarboxylase 65 | IA-2A Insulinoma-associated antigen 2

IAA Insulin autoantibody | ICA Islet cell autoantibody

ZnT8 Zinc transporter-8 autoantibody | No positive antibodies

Antibodies have not been checked | Other

Antibody testing source

Quest Diagnostics | TCH Lab

LabCorp | Other commercial lab

TrialNet | Autoimmunity Screening for Kids (ASK)

Enable Biosciences (online ordering) | Antibodies have not been checked

Other

Is the patient monitoring blood glucose levels at home?

Yes, with CGM | Yes, with blood glucose meter | No | Other

Has patient received teplizumab (TZIELD)? (if yes, puts patient on TZIELD registry)

yes | no

Has the patient received any other diabetes prevention medications?

yes | no

What diabetes prevention medications has the patient received?

test

Teplizumab (TZIELD) Details

Date teplizumab (TZield) was received (start date)

Did patient receive all 14 doses of TZield?

yes | no

TZIELD infusion location

All doses received in TCH infusion center

All doses were received at outpatient infusion center other than TCH

All doses were given in home setting by infusion center other than TCH

Business days at infusion center / weekends home healthcare infusion

Hybrid model (explain)

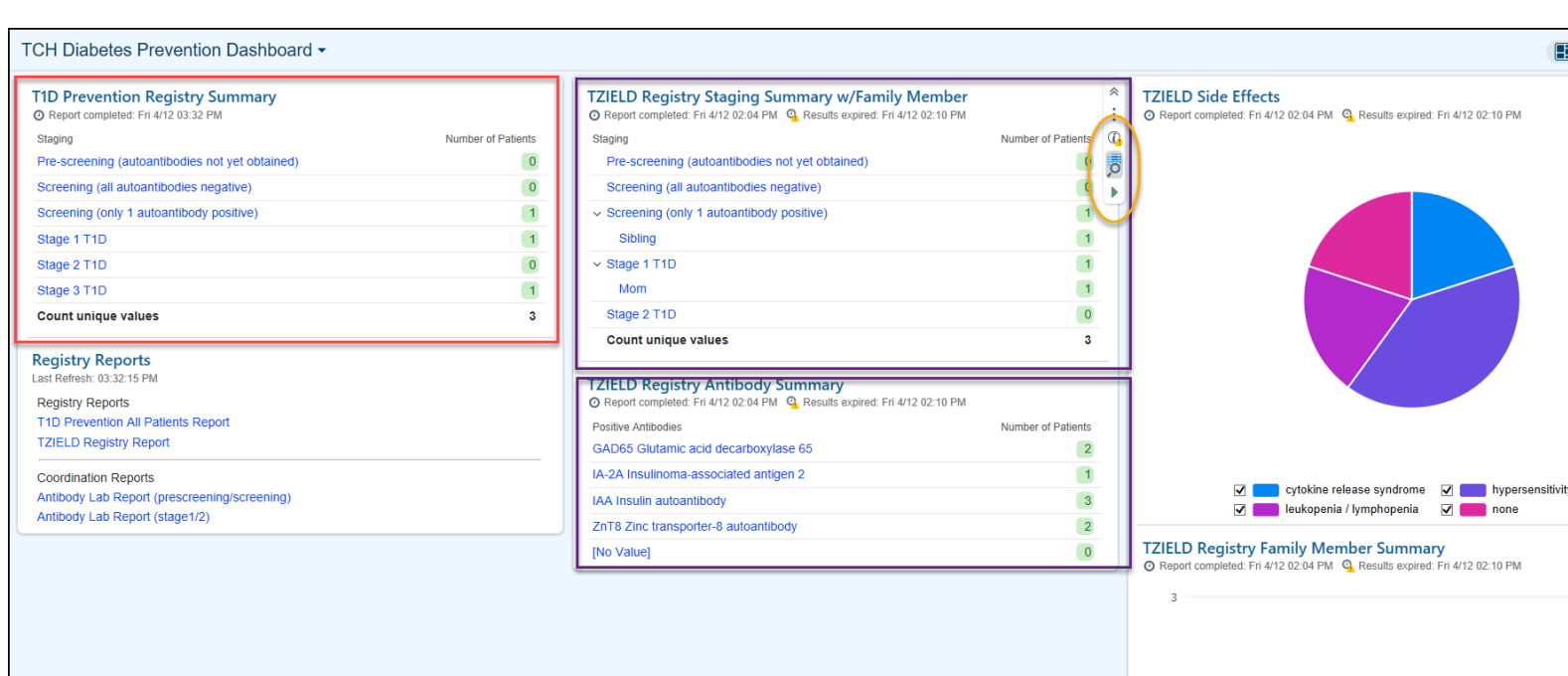
What significant side effects did the patient experience?

cytokine release syndrome | leukopenia / lymphopenia | serious infection

hypersensitivity | rash | elevated LFTs (AST >3x upper limit)

none | other

T1D Screening & Staging Registry - Dashboard



Primary Column	Jan 2024	Feb 2024	Mar 2024
Screening			
A) Number of individuals seen in reporting month who have been screened for T1D antibodies			
Autoantibody Screening			
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Stage 1 Diagnosis			
2) Number of individuals in [A] who have multiple islet autoantibodies, normal blood glucose			
Stage 2 Diagnosis			
3) Number of individuals in [A] who have multiple islet autoantibodies, abnormal glucose tolerance OR HbA1c >= 6.5-6.4%			
Stage 3 Diagnosis/New Onset Patients			
4) Number of individuals in [A] who have blood glucose levels above ADA diagnostic thresholds OR HbA1c >= 6.5%			
Monitoring			
5) Number of individuals in [2] + [3] with a scheduled endocrinology (per monitoring guidelines)*			
DKA Events			
6) Number of individuals monitored for T1D diagnosis in last 12 months who have a DKA in reporting month			
Intervention			
7) Number of individuals in [4] offered Teplizumab prescription			

T1D Screening & Staging - Report

Endocrine T1D Prevention All Patients Report [13006374] as of Fri 4/12/2024 3:32 PM

Chart | Encounter | Communication | Results Review | Place Orders | Questionnaire Series | Research Studies | Synopsis

Detail List | Explore | Diabetes Staging

Filter | Clear All Filters | Re-run Rep

MRN	Patient	Age	Gender	Race	Ethnicity	Staging	Family Member
1569007175	Beacon, Luke	23 y.o.	Male	White	Not Hispanic or Not Latino [1]	Stage 3 T1D	Sibling Mom Uncle

Family Member
TCH ENDO TZIELD FAMILY MEMBER WITH T1D (SF) [2105101]
This column displays the patient's affected family member as documented in the T1D Prevention smartform. [TCH#2480]

JDRF T1D Monitoring

Start of Block: Provider Demographics

Thank you for taking the time to complete this survey. Please fill out the below information before beginning.

Please indicate your clinic affiliation

- Rady Children's (4)
- University of Florida (5)

Name of person completing report

End of Block: Provider Demographics

Start of Block: Individual Demographics

Please answer the following questions for a positively screened individual with T1D Antibodies

*

Age of individual screened (years)



Type 1 Delay Diabetes Clinics Children's National Hospital

What, Why and How?

- We are seeing more and more referrals for potential early type 1 diabetes patients (Stage 1 and Stage 2)
 - A1c 5.7%-6.4%
 - BMI <85th percentile or at a clear pre-pubertal age
- These patients could be:
 - Stage 1 or Stage 2 Type 1 Diabetes
 - MODY
 - Normal A1c on repeat
- Will be put in schedule labeled as a New Type 1 Visit

What do we do during this visit?

- Assess for symptoms of diabetes, history of autoimmune diseases
- Assess for family history of diabetes, MODY
- Check A1c level via POC (confirm with venous blood if have concerns)
- Check diabetes antibodies (consider checking thyroid levels, thyroid antibodies, celiac antibodies based on likelihood of type 1 diabetes)
- Teach glucometer and have them monitor blood sugars for 2 weeks
 - Fasting and 2 hours after dinner

What to do after visit

- IF positive antibodies:
 - Follow-up yearly:
 - 1 positive antibody and normal blood sugars
 - Follow-up every 6 months:
 - 1 positive antibody and normal blood sugars
 - 2 positive antibodies and normal blood sugars + ≥ 5 years of age*
 - Follow-up every 3 months:
 - 2 positive antibodies and normal blood sugars + < 5 years of age*
 - 2 positive antibodies and abnormal blood sugars in Stage 2 range (fasting 100-125, random 140-199, A1c 5.7%-6.4%)*
- IF negative for antibodies: Currently low risk for developing diabetes (but still possible!)
 - Family or personal history of autoimmune disease? \rightarrow consider repeating antibodies in 1 year
 - No family or personal history of autoimmune disease? \rightarrow discuss signs/symptoms of diabetes
 - Concern for MODY? <https://www.diabetesgenes.org/exeter-diabetes-app/ModyCalculator>
 \rightarrow MODY testing

***2 positive antibodies can either:**

- **Discuss with family about 2+ antibodies and progression to clinical diabetes**
- **Discuss with family if they want to learn more about Tzield and if so, send an email to T1DELAYPROGRAM@childrensnational.org and Jody or Shideh will make an appointment with family to discuss Tzield further**
 - **Provider can go ahead and order OGTT before Jody/Shideh meet with them if family is aware of Tzield and considering moving forward with it**



Lurie Children's Hospital of Chicago

Type 1 Diabetes Screening

Laura Levin DO and Naomi Fogel
MD

Ann & Robert H. Lurie
Children's Hospital of Chicago
Pediatric endocrinology




Overview – Lurie Children's Hospital

- Freestanding children's hospital in downtown Chicago
 - 336 patient beds
 - Endocrinology team
 - 15 physicians total - 6 see diabetes patients
 - 3 diabetes APNs
 - 5 hospital-based diabetes educators
 - 9 clinic-based diabetes educators
 - 3 dietitians (2 also CDCES)
 - 2 psychologists and 2 Social workers
- 1400 Type 1 Diabetes patients
 - 50% private insurance, 50% Medicaid
 - 91% CGM use, 55% pump use

Screening for T1D

- Goal to discuss family screening for Type 1 diabetes with all Type 1 families at least once a year.
 - After the initial discussion:
 - Providers will document in new flowsheet row (to be pulled into visit note)

Discussed diabetes screening for family members

Yes No Discussed at previous visits 

- Can use dot phrase for AVS information (next slide)
- For TrialNet: Ask family to email endocrineresearch@luriechildrens.org
- Can refer to asktheexperts.org
- PCP can draw labs if comfortable- working on smartphrase to share
- Can offer telehealth visit for siblings and then our clinic can order the antibodies

Dot phrase in After Visit Summary

How family members can be screened for Type 1 Diabetes:

- **TrialNet:** A free, research-based screening and clinical trial program for family members of people with type 1 diabetes. Screening can be done [through an at-home kit](#) or [in-person](#). The program is available for individuals between the ages of 2.5 and 45 years with a first-degree relative (parent, child, sibling) with T1D, ages 2.5 to 20 with a second-degree relative (cousin, grandparent) with T1D, OR ages of 2.5 to 45 years and have tested positive for at least one T1D related autoantibody outside of TrialNet. <https://www.trialnet.org/> or email endocrineresearch@luriechildrens.org.



- **ASK (Autoimmunity Screening for Kids):** Provides screening for T1D and celiac disease for all children ages 1-17 years in the United States. No family connection to T1D is required to participate in the ASK program. <https://www.askhealth.org>
- **Blood tests ordered by your primary care doctor:** Your doctor (or your child's doctor) can order labs to detect T1D autoantibodies and the cost may be covered by your insurance. Testing labs that currently provide this service in the United States include:
 - Mayo Laboratories
 - LabCorp
 - Quest Diagnostics

Ask the Experts website:





Indiana University School of Medicine

Early-Stage Type 1 Diabetes Program at IU

Started: November 2022

Clinic Frequency: Monthly

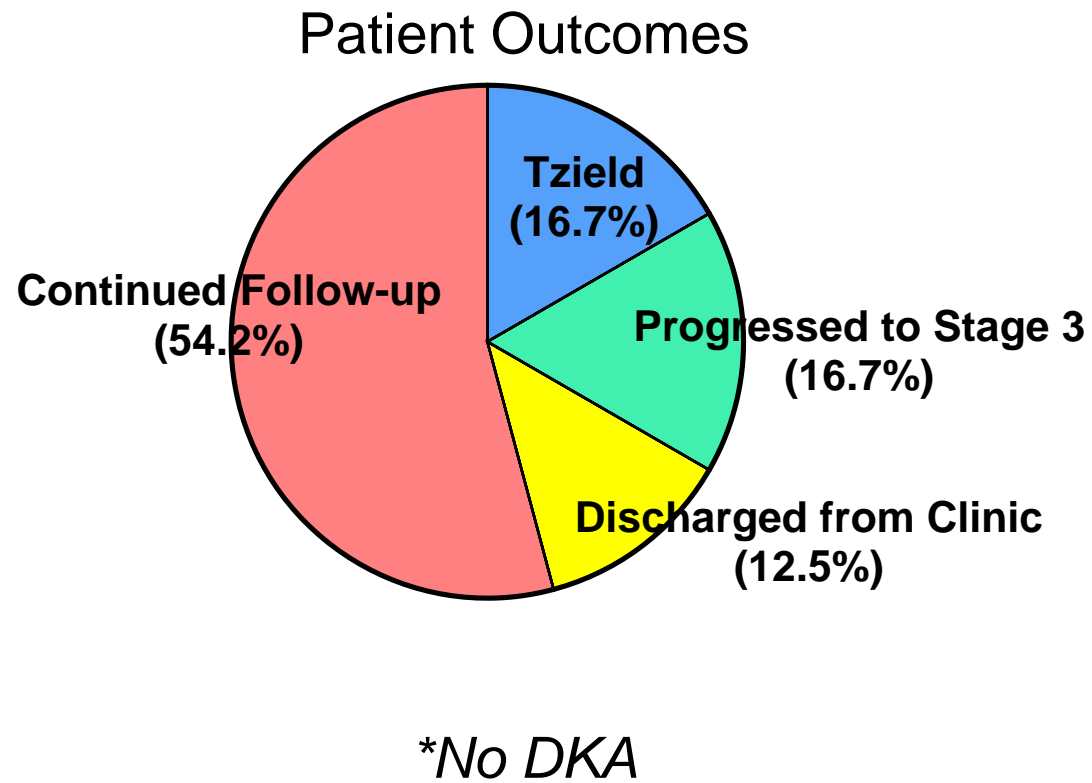
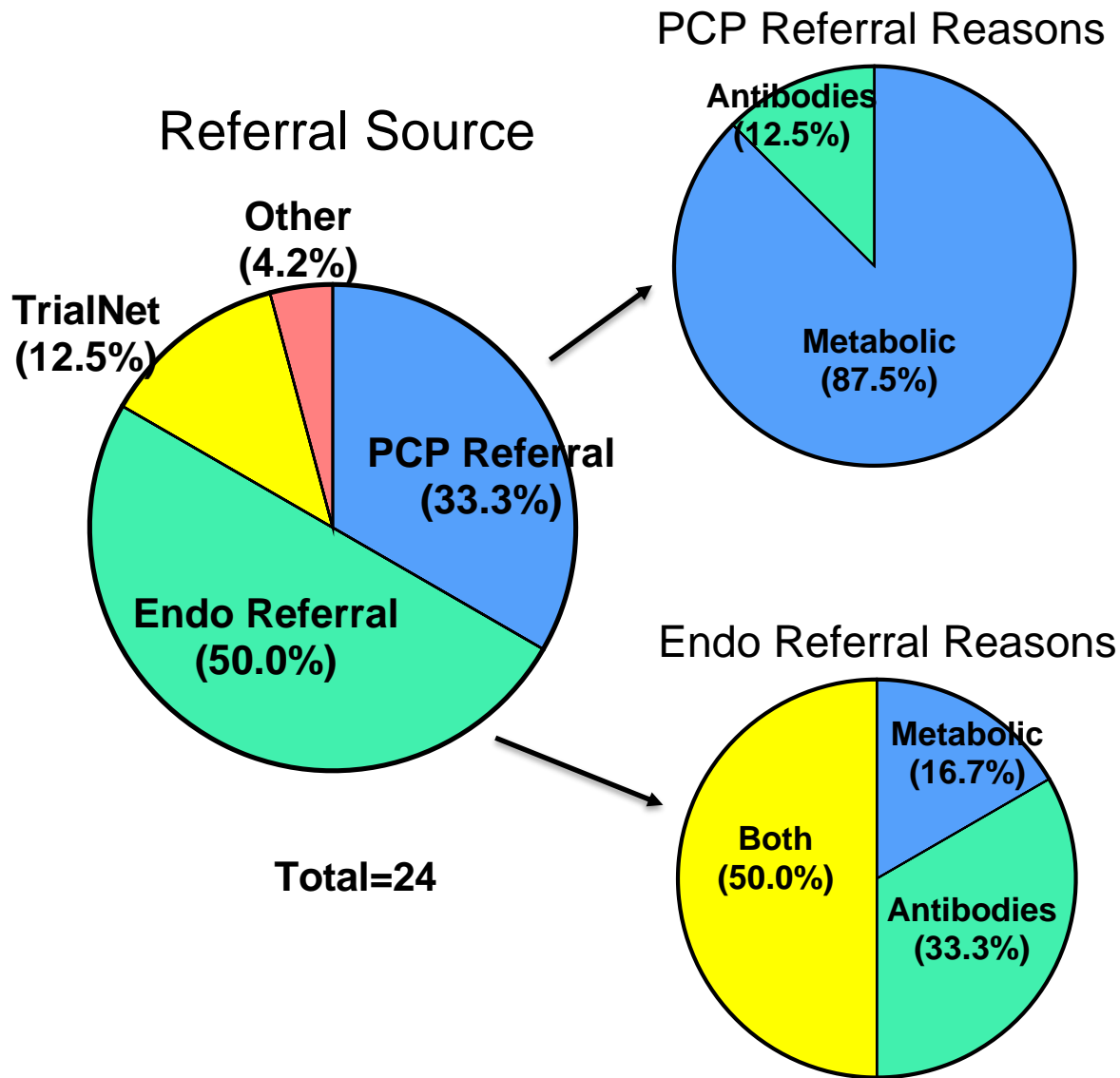
Who is Early-Stage Clinic for?

Anyone without a stage 3 T1D diagnosis who may be at risk (based on family history, autoantibodies, abnormal glucose tolerance, abnormal HbA1c).

What is the Purpose of Early-Stage Clinic?

- 1) To manage/provide appropriate care for individuals with stage 1 and stage 2 T1D.
- 2) To ensure that individuals at risk for development of T1D are appropriately screened and followed.
- 3) To connect individuals to opportunities for therapy and research prior to stage 3 T1D diagnosis.





Next Steps

- Schedule monthly group calls.
- Report data on Smartsheet.

